

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Imran Ahmed

:Examiner: E. Peselev

SERIAL NO.: 09/200,119

:Art Unit: 1623

FILED: November 25, 1998

FOR: Method Of Treating Eye
Infections With Azithromycin

I hereby certify that this correspondence
is being deposited with the United States
Postal Service as First Class Mail in an
envelope addressed to: Assistant Commissioner
for Patents, Washington, D.C. 20231 on

Assistant Commissioner For Patents
Washington, D.C. 20231this 12th day of November 2001

Sir:

By DECLARATION UNDER RULE 131

I, Imran Ahmed, declare that:

1. I received my Bachelor of Science degree in Pharmacy from the University of Michigan in 1980, my Master of Science Degree in Pharmaceutical Chemistry from the University of Kansas in 1982, and my Ph.D. in Pharmaceutical Chemistry from the University of Kansas in 1985. I was Assistant Professor of Pharmaceutics at the University of Northeast Louisiana until 1987.
2. I have worked at Pfizer Inc. since January, 1987, primarily in the area of dosage form development for new chemical entities. My current title is Assistant Director, Pharmaceutical R&D.
3. I am the inventor in the above-identified application in which a Notice of Appeal was mailed on May 16, 2001, and am aware of the Office Action dated November 17, 2000. In particular, I am aware that claims 1-6 and 8-9 stand rejected under 35 USC 102(a) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over First Meeting of the WHO Alliance For The Global elimination of Trachoma, Geneva, 30 June-1 July 1997 (hereinafter the "WHO reference").
4. Under my guidance and direction, in an albino rabbit model, I tested a topically applied ocular composition comprising 0.5 % azithromycin dihydrate dispersed into a commercially obtained, sterile ointment vehicle (Tearfair™). The active azithromycin composition was tested against a placebo control, with azithromycin topical ocular composition being instilled into the left eye and placebo into the right eye in each animal.

5. After conducting the study cited in paragraph 4 above, I co-authored a memorandum which summarized the results of the study. A page from that memo bearing Table 2 is attached hereto as Exhibit 1. The Table summarizes individual tissue concentrations (μg azithromycin/g tissue) in the eye of each rabbit following the instillation of a single dose of azithromycin ophthalmic ointment or placebo.

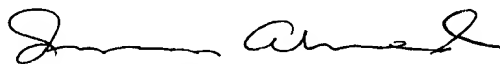
6. The memorandum was acknowledged and "signed off" as either having been authored, reviewed and approved, or approved for distribution by a number of scientists and/or employees within Pfizer, in addition to myself. This is demonstrated by page 3 from the memorandum on which the signatures appear, which page is attached hereto as Exhibit 2. Page 3 also evidences the conclusions from the rabbit study described above, definitively demonstrating that a topical ocular ointment and the corresponding method of topically applying the topical azithromycin ocular ointment to the eye were reduced to practice.

7. The study described in paragraph 4 was conducted, and the memorandum described in paragraphs 5 and 6 was written and issued, prior to 30 June-1 July, 1997, the date of the WHO reference.

8. In addition to the WHO reference, I acknowledge that I am aware of a contact made to Pfizer by an outside party inquiring about azithromycin in a topical formulation for use in the eye, as evidenced by a letter received within Pfizer, attached hereto as Exhibit 3. The study described in paragraph 4 was conducted, and the memorandum described in paragraphs 5 and 6 was written and issued, prior to the date of the letter, and prior to the date any such contacts by the third party occurred.

9. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

November 9, 2001
Date


Imran Ahmed